

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
 PRATT, John
 PRATT, John S.
 Suite 2800
 1100 Peachtree Street,
 Atlanta, GA 30309
 ETATS-UNIS D'AMERIQUE

NOTIFICATION OF TRANSMITTAL OF
 THE INTERNATIONAL SEARCH REPORT AND
 THE WRITTEN OPINION OF THE INTERNATIONAL
 SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 51687/382207	Date of mailing <i>(day/month/year)</i> <div style="text-align: right;">6 October 2010 (06-10-2010)</div>
International application No. PCT/US2009/058498	International filing date <i>(day/month/year)</i> <div style="text-align: right;">25 September 2009 (25-09-2009)</div>
Applicant TRANSGENRX, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
 1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders


Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, National Chapters.

Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016	Authorized officer EIDEL, Clémence Tel: +31 (0)70 340-2670
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NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Annex B).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, International Phase, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet or sheets containing a complete set of claims in replacement of all the claims previously filed must be submitted.

Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively in Arabic numerals (Section 205(a)).

The amendments must be made in the language in which the international application is to be published.

What documents must/accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1 *bis*(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43 *bis*.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, National Chapters.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 51687/382207	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2009/058498	International filing date (<i>day/month/year</i>) 25/09/2009	(Earliest) Priority Date (<i>day/month/year</i>) 25/09/2008
Applicant TRANSGENRX, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6**bis**(a)).

c. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 3
☒ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention
 b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2009/058498

Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.b of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:
 - a. (means)

☒

 on paper

☒

 in electronic form
 - b. (time)

☒

 in the international application as filed

☐

 together with the international application in electronic form

☒

 subsequently to this Authority for the purpose of search
2.

☒

 In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/058498

A. CLASSIFICATION OF SUBJECT MATTER
INV. C07K14/465 C12N15/85
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
C07K C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, Sequence Search, WPI Data, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/003157 A2 (TRANSGENRES LLC [US]; UNIV LOUISIANA STATE [US]; COOPER RICHARD K [US]) 8 January 2004 (2004-01-08) The whole document, in particular p.4 par.2; p.12 last. par.; p.23 par.2; p.30 ln.5-9; Example 18 and the claims. -----	1, 11, 13, 15, 16
X	WO 2004/067707 A2 (TRANSGENRES LLC [US]; UNIV LOUISIANA STATE [US]; COOPER RICHARD K [US]) 12 August 2004 (2004-08-12) The whole document, in particular p.4 par.2; p.12 par.4; p.24 par.1; p.30 ln.14-18 and the claims. ----- -/--	1, 11, 13, 15, 16

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

20 September 2010

Date of mailing of the international search report

06/10/2010

Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Lonnoy, Olivier

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/058498

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DATABASE Geneseq [Online] Derwent; 13 December 2007 (2007-12-13), Blatt LM et al: "Human variant interferon-alpha 2b protein SEQ ID NO: 1440." XP002601423 Database accession no. ANK84991 the whole document</p>	16-18
X	<p>-& DATABASE Geneseq [Online] Derwent; 13 December 2007 (2007-12-13), Blatt LM et al: "Human variant interferon-alpha 2b DNA SEQ ID NO: 1818" XP002601424 Database accession no. ANK85305 the whole document</p>	16-18
A	<p>----- GEYER P K ET AL: "Protecting against promiscuity: The regulatory role of insulators" CMLS CELLULAR AND MOLECULAR LIFE SCIENCES, BIRKHAUSER VERLAG, HEIDELBERG, DE LNKD- DOI:10.1007/S000180200011, vol. 59, no. 12, 1 December 2002 (2002-12-01), pages 2112-2127, XP002573586 ISSN: 1420-682X table 1</p>	15
A	<p>----- WO 2004/065581 A2 (DISCOVERY GENOMICS INC [US]) 5 August 2004 (2004-08-05)</p>	1-18
A	<p>----- LARGAESPADA DAVID A: "Generating and manipulating transgenic animals using transposable elements" REPRODUCTIVE BIOLOGY AND ENDOCRINOLOGY, XX, XX LNKD- DOI:10.1186/1477-7827-1-80, vol. 1, no. 1, 7 November 2003 (2003-11-07), page 80, XP021009352 ISSN: 1477-7827 table 1</p>	1-18
A	<p>----- KOZAK ET AL: "At least six nucleotides preceding the AUG initiator codon enhance translation in mammalian cells" JOURNAL OF MOLECULAR BIOLOGY, LONDON, GB LNKD- DOI:10.1016/0022-2836(87)90418-9, vol. 196, no. 4, 20 August 1987 (1987-08-20), pages 947-950, XP024010432 ISSN: 0022-2836 [retrieved on 1987-08-20] -----</p>	1-18
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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/058498

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>MAKSIMENKO O G ET AL: "Insulators of higher eukaryotes: properties, mechanisms of action, and role in transcriptional regulation"</p> <p>RUSSIAN JOURNAL OF GENETICS, MOSCOW, RU, vol. 42, no. 8, 1 August 2006 (2006-08-01), pages 845-857, XP002573587</p> <p>ISSN: 1022-7954</p> <p>-----</p>	1-18

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2009/058498

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2004003157	A2	08-01-2004	AT 430756 T 15-05-2009
		AU 2003261096 A1 19-01-2004	
		BR 0305217 A 28-06-2005	
		CA 2490693 A1 08-01-2004	
		EP 1539785 A2 15-06-2005	
		JP 2005530516 T 13-10-2005	
WO 2004067707	A2	12-08-2004	AT 431849 T 15-06-2009
		AU 2003299959 A1 23-08-2004	
		AU 2003303830 A1 23-08-2004	
		AU 2003303831 A1 23-08-2004	
		EP 1592789 A2 09-11-2005	
		EP 1597378 A2 23-11-2005	
		JP 2006512921 T 20-04-2006	
		JP 2006512922 T 20-04-2006	
		WO 2004067706 A2 12-08-2004	
		WO 2004067743 A1 12-08-2004	
WO 2004065581	A2	05-08-2004	NONE

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2009/058498

International filing date (day/month/year)
25.09.2009

Priority date (day/month/year)
25.09.2008

International Patent Classification (IPC) or both national classification and IPC
INV. C07K14/465 C12N15/85

Applicant
TRANSGENRX, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040
Fax: +31 70 340 - 3016

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Lonnoy, Olivier

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2009/058498

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:
- a. (means)
- ☒ on paper
 - ☒ in electronic form
- b. (time)
- ☒ in the international application as filed
 - ☐ together with the international application in electronic form
 - ☒ subsequently to this Authority for the purposes of search
4. ☒ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>2-10, 12, 14</u>
	No: Claims	<u>1, 11, 13, 15-18</u>
Inventive step (IS)	Yes: Claims	<u>7-10</u>
	No: Claims	<u>1-6, 11-18</u>
Industrial applicability (IA)	Yes: Claims	<u>1-18</u>
	No: Claims	

2. Citations and explanations

see separate sheet

V. Reasoned statement (Continuation)

1. The present application relates to vectors comprising a modified transposase gene, a promoter with modified Kozak sequence, transposon insertion sequences recognized by the transposase and flanking a multiple cloning site, and an insulator element (claims 1-6). Furthermore promoters comprising chicken ovalbumin promoter regulatory elements in combination with a CMV enhancer and a CMV promoter (claims 7-8), or comprising a steroid dependent response element, a CMV enhancer, a chicken ovalbumin negative response element and a CMV promoter are claimed (claims 9-10). A vector and a method for producing an interferon are also claimed (claims 5 and 11-14), as well as human interferon (claim 16), an interferon comprising SeqIdNo.29 and nucleotide sequence encoding it (claims 17-18) and an insulator (claim 15).

2. CITATIONS

Reference is made to the following documents:

- D1 WO 2004/003157 A2 (TRANSGENRES LLC [US]; UNIV LOUISIANA STATE [US]; COOPER RICHARD K [US]) 8 January 2004 (2004-01-08)
- D2 WO 2004/067707 A2 (TRANSGENRES LLC [US]; UNIV LOUISIANA STATE [US]; COOPER RICHARD K [US]) 12 August 2004 (2004-08-12)
- D3, D4 DATABASE Geneseq [Online] Derwent; 13 December 2007 (2007-12-13) , Blatt LM et al: "Human variant interferon-alpha 2b protein SEQ ID NO: 1440." Database accession no. ANK84991 ; -& DATABASE Geneseq [Online] Derwent; 13 December 2007 (2007-12-13), Blatt LM et al: "Human variant interferon-alpha 2b DNA SEQ ID NO: 1818" Database accession no. ANK85305
- D5 GEYER P K ET AL: "Protecting against promiscuity: The regulatory role of insulators" CMLS CELLULAR AND MOLECULAR LIFE SCIENCES, BIRKHAUSER VERLAG, HEIDELBERG, DE LNKD- DOI:10.1007/S000180200011, vol. 59, no. 12, 1 December 2002 (2002-12-01) , pages 2112-2127, XP002573586 ISSN: 1420-682X

3. D1 and D2, from the same inventors as the present application, disclose both transposon-based vectors for producing transgenic animals that express proteins of interest. The transposon-based vectors comprise all the elements as described in

claim 1. The regulatory sequences which are part of the vectors of D1 and D2 comprise also insulator elements (e.g. p.12 last paragraph and page 83 line 13 of D1). Said regulatory sequences can be linked to the gene of interest (goi) to be expressed, hence they are located between the transposon insertion sequence and the multiple cloning site (mcs) as claimed, since the goi is in the mcs which is flanked by the transposon insertion sequences. Matrix attachment sites are also disclosed in D1 and in D2 (e.g. p.12 ln.31 of D1). Interferons are mentioned as genes to be expressed (e.g. p.30 ln.5-9 of D1). Consequently, the subject-matter of claims 1, 11, 13, 15 and 16 is not in accordance with Article 33(2) PCT in view of D1 or D2.

4. D3 and D4 describe respectively an Interferon comprising SeqIdNo.29 and a nucleotide sequence encoding said Interferon. They deprive claims 17 and 18 of novelty (Article 33(2) PCT). The human Interferon in claim 16 is not distinguishable from human Interferon produced by another method. Hence, any prior art document describing human Interferon (e.g. D3, D4), anticipates the subject-matter of claim 16 (Article 33(2) PCT).

5. Claims 2-6, 12, and 14 refer to vectors according to claim 1 having specific sequences. All said specific sequences appear to be novel. However, since the general concept of the vector as described in claim 1 is known (see paragraph 3 of this communication), all said vectors appear to represent obvious, arbitrarily chosen examples of said concept and thus said claims do not meet the requirements of Article 33(3) PCT.

6. Claim 15 describes specific insulator elements. However, a skilled person knows different insulators and their functions. Furthermore, review articles like D5 exist which refer to said insulators. Consequently, the combination of the teaching of D1 or D2 with D5 would lead to vectors having the specific insulators as described in claim 15 (Article 33(3) PCT).

7. Claim 13 is not restricted to the vectors of the previous claims but refers to any vector comprising a modified gene encoding for a transposase, a promoter and a gene encoding for an interferon. The method as presently claimed in this broad manner is already anticipated by D1 or D2 (see paragraph 3 of this opinion). Should the method be rendered novel over said prior art due to minor differences, it has to be

emphasized that such a broad claim is not considered inventive, since it does not comprise any special technical features which are not within the ordinary skills of a person skilled in the art producing interferons (Article 33(3) PCT).

8. Expressions like “incorporated herein/hereby by reference” used in the description render the true scope of the application unclear and are thus not in accordance with Article 6 PCT. The same applies for the use of expressions like “spirit of the invention”.

9. Only the specific promoters of claims 7-10 appear to meet the requirements of the PCT. However, the advantage/superiority of these specific promoters over already known promoters might be discussed in the regional phase.

10. It is noted that the present set of claims relates to multiple inventions which are not so linked as to form a single general inventive concept: there is thus lack of unity of invention. Any set of amended claims could only be allowed if all claimed subject-matter is then linked by a single general inventive concept.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	<p>For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.</p>
Amending claims under Art. 19 PCT	<p>Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.</p>
Filing a demand for international preliminary examination	<p>In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).</p> <p>If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).</p>
Filing informal comments	<p>After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.</p>
End of the international phase	<p>At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).</p>
Relevant PCT Rules and more information	<p>Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003</p>

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